

VASODILAN - isoxsuprine hydrochloride tablet

Bristol-Myers Squibb Company

INDICATIONS

Based on a review of this drug by the National Academy of Sciences-National Research and/or other information, the FDA has classified the indications as follows:

Possibly Effective:

1. For the relief of symptoms associated with cerebrovascular insufficiency.
2. In peripheral vascular disease of arteriosclerosis obliterans, thromboangitis obliterans (Buerger's disease) and Raynaud's disease.

Final classification of the less-than-effective indications requires further investigation.

COMPOSITION

Vasodilan (isoxsuprine HCl tablets, USP) 10 mg and 20 mg. These tablets contain the following inactive ingredients: acacia, dibasic calcium phosphate, lactose, magnesium stearate, starch (corn), and talc.

DOSAGE AND ADMINISTRATION

Oral: 10 to 20 mg, three or four times daily.

CONTRAINDICATIONS AND CAUTIONS

Oral

There are no known contraindications to oral use when administered in recommended doses. Vasodilan should not be given immediately postpartum or in the presence of arterial bleeding.

ADVERSE REACTIONS

On rare occasion oral administration of the drug has been associated in time with the occurrence of hypotension, tachycardia, chest pain, nausea, vomiting, dizziness, abdominal distress, and severe rash. If rash appears, the drug should be discontinued.

Although available evidence suggests a temporal association of these reactions with isoxsuprine, a causal relationship can be neither confirmed nor refuted.

β -Adrenergic receptor stimulants such as isoxsuprine hydrochloride have been used to inhibit pre-term labor. Maternal and fetal tachycardia may occur under such use. Hypocalcemia, hypoglycemia, hypotension and ileus have been reported to occur in infants whose mothers received isoxsuprine. Pulmonary edema has been reported in mothers treated with β -stimulants. Vasodilan (isoxsuprine HCl tablets, USP) is neither approved nor recommended for use in the treatment of premature labor.

SUPPLIED

Vasodilan[®] (isoxsuprine HCl tablets, USP)

10 mg

Bottles of 100 NDC 0087-0543-01

Bottles of 1000 NDC 0087-0543-02

Unit Dose NDC 0087-0543-05

Vasodilan[®] (isoxsuprine HCl tablets, USP)

20 mg

Bottles of 100 NDC 0087-0544-01

Bottles of 1000 NDC 0087-0544-06

MeadJohnson Pharmaceuticals

A Bristol-Myers Squibb Company, Princeton, New Jersey 08543 U.S.A.